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| Notice of Allowability | Application No. | Applicant(s) | |
| | 10/036,828 | QIAO ET AL. | |
| | Examiner | Art Unit | |
| | BJ Forman | 1634 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--
All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Amendments of 3 June 2005 and interview of 2 August 2005.
2. ☒ The allowed claim(s) is/are 1-25.
3. ☒ The drawings filed on 29 April 2002 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No./Mail Date <u>0805</u> . |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |


BJ FORMAN, PH.D.
PRIMARY EXAMINER

NOTICE OF ALLOWABILITY

Status of the Claims

1. This action is in response to papers filed 3 June 2005 in which claims 1 and 21 were amended and further in response to amendments agreed upon during an interview between Ms. Mann and the examiner on 2 August 2005.

All of the amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 12 April 2005 are withdrawn in view of the amendments. The amendments place the claims in condition for allowance.

Claims 1-25 are in condition for allowance.

EXAMINER'S AMENDMENT

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Kathleen Neuner Manne on 2 August 2005.

The application has been amended as follows:

Replace Claim 1 with the following:

Claim 1. A method of identifying biological samples comprising:
providing a microarray including a substrate having no preselected sites for association with micro-spheres wherein providing comprises coating said substrate coated with a composition including a population of micro-spheres dispersed in a fluid containing gelatin and

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immobilizing said micro-spheres ~~immobilized~~ in a single layer of single micro-spheres at random positions and at ~~with~~ a uniform density on the substrate, at least one sub-population of said population of micro-spheres containing an optical barcode generated from at least one colorant associated with the micro-spheres and wherein said microspheres have ~~including~~ a biological probe attached thereto; contacting said microarray with a biological target sample; detecting the optical barcode of said sub-population of micro-spheres due to the interaction of said biological probe and said biological target sample; and identifying said biological sample.

Replace Claim 21 with the following:

Claim 21. A method of identifying biological samples comprising: providing a microarray wherein providing comprises coating ~~including~~ a substrate ~~coated~~ with a composition including a population of micro-spheres dispersed in a fluid containing gelatin and immobilizing ~~immobilized in~~ a single layer of single micro-spheres at random positions at ~~with~~ a uniform density on the substrate wherein the substrate has ~~having~~ no preselected sites for association with micro-spheres, at least one sub-population of said population of micro-spheres containing an optical barcode generated from at least one colorant associated with the micro-spheres, said colorant having one of a luminescent or fluorescent property and wherein said micro-spheres ~~have~~ including a biological probe sequence attached thereto; contacting said microarray with a biological target sample; and detecting the optical barcode of said sub-population of micro-spheres due to the interaction of said probe and said target by:

- (a) whole frame imaging of the luminescent or fluorescent image resulting from said interaction to produce a first image;
- (b) whole frame imaging capture of said microarray under bright field illumination to obtain the micro-sphere optical barcode to produce a second image; and
- (c) processing said first and second images to obtain identification of said biological sample.

REASONS FOR ALLOWANCE

3. The following is an examiner's statement of reasons for allowance:

The claims are drawn to a method for sample identification. The method steps provide a microarray of probe-attached microspheres, uniformly and randomly immobilized on a substrate forming a single layer of single microspheres in gelatin. The closest prior art (Sutton et al U.S. Patent No. 5,714,340) teaches immobilization of microspheres in a polymer coating (Columns 9-10) but they specifically teach that gelatin coating destroys the binding capacity of antibodies on the microspheres (Column 14, lines 29-45). Therefore, the closest prior art specifically teaches away from the claimed invention.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

4. Claims 1-25 are allowed.
5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.


Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.


BJ Forman, Ph.D.
Primary Examiner
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August 2, 2005